Summary Business Plan

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Executive Summary

Legendairy is a startup focused on developing novel and effective solutions to bovine mastitis to help the dairy industry and public health. We aim to solve this issue in three stages: prevention, detection, and treatment. Bovine mastitis is a disease that affects dairy farms and results in abnormal milk and swelling in the cow. It results in about $2 billion in loss in the US and the heavy usage of antibiotics in a critical food source.

To prevent the disease, we have designed a novel milking shell to attach to existing dairy farm milking machines. The process of milking leaves cows vulnerable to infection. The milking shell is modular, which allows the farmers to choose from four functionalities including automated teat dipping, cold shock, UV-C lights, and temperature sensing. We have also developed a mobile app to detect and monitor the disease more effectively with three components Somatic Cell Counter, a Cost Calculator, and Cow Data. These will help farmers detect mastitis earlier and easier.

To market our products we are focusing on our unique selling proposition of being the only non-antibiotic mastitis solution that could be on the market. We will emphasize our products as being safer, healthier, and better for the cows. Through our market analysis we believe that our products will be able to be the foundation of a sustainable business.

Industry Analysis

Industry Rivalry

We will likely face competition from large pharmaceutical companies who produce antibiotic treatments from bovine mastitis, though we will not be direct competitors since our treatment is not an antibiotic. We may also face competition from other startups looking for an alternative treatment, but strong competition in that respect is not certain.

Threat of Substitutes

The most common treatment for bovine mastitis is currently antibiotics, which makes it an established possible substitution for Legendairy. Alternatively, dairy producers may also choose to not treat the cows and instead replace them with new cows, but this option is likely not as cost efficient as treating the diseased cows.

Bargaining Power of Buyers

Dairy producers make opt to use the antibiotic treatments because they are more familiar, more established, and cheaper at purchase. They may make the case that antibiotics are easier to use and limit our ability to sell at a profitable price. In general, the novelty and unfamiliarity of Legendairy may drive potential buyers away from the treatment unless they are addressed.

Bargaining Power of Suppliers

Since our product requires many unique components, suppliers might drive up their asking price due to a lack of alternatives from their competitors. Manufacturers may charge larger contracting fees because of the specificity of our treatment system and monitoring shell. Because they might need new, specialized equipment, they have leverage in driving up costs.

Barriers to Entry

Entry into any disease treatment market requires extensive R&D for efficacy and safety, which is often a huge resource and financial cost that is only affordable to certain organizations or groups. New competitors will also need to obtain licensing and FDA approval for the new treatment and compete with the large market footprint of large, established pharmaceutical companies.

Company Description

Legendairy was conceived in the summer of 2016 by Cornell's iGEM project team. The company would provide a prevention treatment for bovine mastitis, which is a disease contracted by cows, marked by the infection and inflammation of the udders, and affects the quality of their milk to an extent where it is unmarketable. Utilizing the research done by the team in 2016, Legendairy would create a marketable product consisting of bacteriocins to treat different types of mastitis and five modules that can be sold separately. One module is a normal shell used in milking machines, while the other four consist of special attachments consisting of a UV light, a temperature detector, a cooling device, and an automatic teat dip. Legendairy has also developed a complementary mobile application with a microscope attachment which gives an accurate somatic cell count of a milk sample. Legendairy would market these technologies to dairy farmers with the goal of making farms more sustainable and

cost-effective, as well as keeping milk products safe for consumers and improving conditions for dairy cows.

Mission and Vision Statement

We at Legendairy believe that sustainable, health-conscious, and efficient dairy production is extremely important with a growing global population and increasingly processed food. The treatment of animals in food production in key in protecting ourselves from chemicals and antibiotics in our food. We envision a future with healthy and sustainable food source and with people who are aware of how their food is processed, and how animals are treated during this process, before it arrives on their plate. Our goal is to decrease the amount bovine mastitis cases, and therefore decrease the need for treatment through antibiotics. We make it our mission to produce a safer way to treat mastitis by utilizing natural proteins, allowing for dairy farmers to provide the highest quality of the milk possible. We are passionate about the health of animals during this food process, and want to make available better preventative treatments for farmers. With these initiatives, Legendairy will help dairy farmers worldwide to attain a more sustainable position for milk production.

Products and Services

The Milky Way Customizable Shell (mastitis prevention milking shell)

When talking to farmers, we found that most farmers place an emphasis on bovine mastitis prevention, since they would rather not see mastitis at all than deal with treatment later. Our Product Development team designed a device with five modules with the aim of achieving this goal. The base component consists of a standardized shell that is used for most milking machines, but with the ability to attach any of the four other modules. The first attachment module are UV-C lights, used to sterilize the inside of the liner between milkings. This is meant to be another method of ensuring the milking process is as sanitary as possible, with no extra effort on the part of the farmer. The second attachment module allows for an automatic teat dip functionality. Many farmers manually dip the cow's teats after milking to lower the risk of bovine mastitis, but automated teat dipping would take less time compared to manually dipping. The third module is a cold shock which utilizes a Peltier device to decrease the temperature of the cow's teats. Studies show that after milking a cow, there is a higher chance of infection due to the vulnerability of an open teat, so cooling the teats should close the teats faster, reducing the time from the average thirty minutes they remain open. Finally the last module detects the temperature of the udder, since it is shown that higher

temperature of the udder usually correlates to greater severity of the infection. This component could allow for earlier detection of the disease.

Cow Scope (mastitis detection mobile app)

The Cow Scope is a mobile app designed to help farmers better manage bovine mastitis on their farms. After consulting local farmers, we decided to build the app with three sections: a Somatic Cell Counter, a Cost Calculator, and Cow Data. Each section focuses on a different part of management for mastitis: detection, individual analysis, and overall analysis.

The Somatic Cell Counter bring the lab to the farm: instead of having samples of milk shipped to the lab to calculate the somatic cell count in the milk, farmers could do it in their own farms using their smartphones and our microscope mount.

The Cost Calculator is used to calculate the costs of treating and maintaining a cow infected with mastitis. It aims to give farmers some quick metrics to weigh the potential financial costs of an infected cow. The cost includes factors such as treatment time, milk product, and milk cost, but we acknowledge that there are more factors that determine the cost of taking care of an infected cow. We hope to include more factors in the future.

The Cow Data section shows farmers trends that may be overlooked in the day-to-day care of farms. It shows graphs such as infection by cow and milk production so that farmers can see if there is a certain cluster of cows that become infected repeatedly, and see how productive each cow is. We hope it highlights trends such as budding mastitis outbreaks, so that farmers can take preventive measures as early as possible.

Udder Defense (mastitis treatment peptide)

We have developed many different bacteriocin proteins. Each bacteriocin specializes in targeting a select few species of pathogens, and a few bacteriocins also display broad spectrum activity. Each bacteriocin treatment will be sold separately. The bacteriocin treatment will be administered using a PLGA polymer based gel that will be injected into the teat through the milking shell. Treatments are available for some of the most common and most virulent pathogens of bovine mastitis. The farmers will be able to test for the type of bacteria causing the bovine mastitis and administer a specialized treatment. If the farmers are not able to test for the bacterial strain in a lab, we have developed broad spectrum bacteriocin treatments that are also effective options. Currently, we are designing and making additional bacteriocins that would broaden the scope of our treatment.

Current Status

Legendairy has not been incorporated yet. Our team is in the process of legally starting the company. When the company is officially started, it will be owned by Cornell University and by members on the Cornell iGEM project team.

Key Partnerships

Legendairy will look to maintain strong partnerships with Cornell University and its faculty for their invaluable resources and expertise. We will also seek to partner with key players in the field of veterinary health within the dairy industry and in the antibiotics alternatives space.

Market Analysis

Demographics and Segmentation

In the United States

According to Progressive Publishing's 2015 statistics, there are 9,317,000 cows in the US and around 209 million pounds milk was produced that year. At the average price of $0.241 per pound of milk, all the milk produced amounts to $50 billion dollars. On average, each cow in the US produced 22400 pounds of milk[1].

Mastitis costs the dairy industry about $1.7 to 2 billion annually, in order words 11% of the total US milk production. Most of the cost is from the lost profit due to the reduced milk production of when cows are affected with mastitis. Apart from the lost profit, costs also include labor, discarded milk, treatment, and veterinary services. Adding all these costs, a cow with mastitis could cost the dairy farmer anywhere ranging from $117[2] to $444[3].

[1] U.S. Dairy Stats - Progressive Dairyman. Retrieved October 19, 2016, from http://www.progressivedairy.com/site/stats/us-dairy-stats

[2] Understanding the Basics of Mastitis. (2009, May 1). Retrieved October 19, 2016, from http://animalwelfareapproved.org/2010/09/27/dairy-cattle-antibiotic-residue-review/

[3] Rollin, E., Dhuyvetter, K. C., & Overton, M. W. (2015, December). The cost of clinical mastitis in the first 30 days of lactation: An economic modeling tool Retrieved October 19, 2016, from http://www.sciencedirect.com/science/article/pii/S0167587715300490

Worldwide

Internationally, there are 264 million dairy cows and they produce about 600 millions tonnes (around 1.3 trillion pounds) of milk per year. United States is the biggest producer of milk and produces around 14.6% of the milk worldwide[4]. The cost of mastitis differs from country to country; it costs Dutch farmers €17 to €198 per average cow per year for example[5].

Summary
Table 1.

	# Cows	Lbs Milk Produced	Annual Loss to Mastitis	% of Total Milk Production Lost
US	9.3 million	2.1 billion	$1.7-2 billion	11%
World	264 million	1.3 trillion	---	---

*total production loss takes into account lost profit from infected milk, treatment costs, and production lost due to infected cows being unusable

The dairy industry, both in the US and worldwide, is enormous. With an estimated domestic market size of $50 billion and an estimated international market size of $313 billion, there is no doubt that it is an industry of consequence. The US is the largest producers of milk in the world, accounting for 14.6% of the total production. In the US alone, bovine mastitis costs the industry an annual loss of up to $2 billion dollars and roughly 11% of the total milk production. With a potential 305 day production loss (21,000 lbs of milk) and $171-300 treatment fee per cow, the need for a more effective treatment is clear.

[4] Compassion in World Farming. (2007, January 7). Retrieved October 19, 2016, from http://www.ciwf.org.uk/

[5] Current status and future challenges in mastitis research. (2011, October 10). Retrieved October 19, 2016, from http://www.milkproduction.com/Library/Scientific-articles/Animal-health/Current-status-and-future-challenges-in-mastitis-research/

Current Mastitis Treatment

Current mastitis treatment is very inefficient and is wasteful. Mastitis is detected from visible swelling and abnormal milk. To find the specific bacterial cause of the mastitis, a milk sample has to be sent to the lab for testing before treatment can begin. Sick cows are then separated from the rest of the cows for weeks. This separation of the cow is necessary but detrimental to the cow as it is stressful to the cow and affects the social structure. They then undergo antibiotic treatment. For a long period the cow can't be milked because the antibiotics are unsafe for human consumption. Often, antibiotic treatment is administered where there is not even any bacterial culture to kill. There are different types of bacteria that cause mastitis and often the wrong antibiotic is administered. This problem contributes to the low cure rate of 50-60%.

In addition to the inefficiencies of current mastitis treatment, it is also very expensive. A single case could cost up to $444 (table below) per cow. Antibiotic treatment costs $60 per case. Somatic cell counts are used for testing. Reducing mastitis saves significant amounts of money for farmers.

Our product is superior to the current solutions in that it does not involve antibiotics, it is more affordable in diagnosis, and it has no negative health implications for the cow. Unlike antibiotics which have negative health implications and carry the risk of resistance, bacteriocins are natural, safe for human consumption, and effective against specific strains of bacterial infection.

Table 2. [6]
Breakdown of estimated cost per case of clinical mastitis in the first 30 days of lactation.[a]

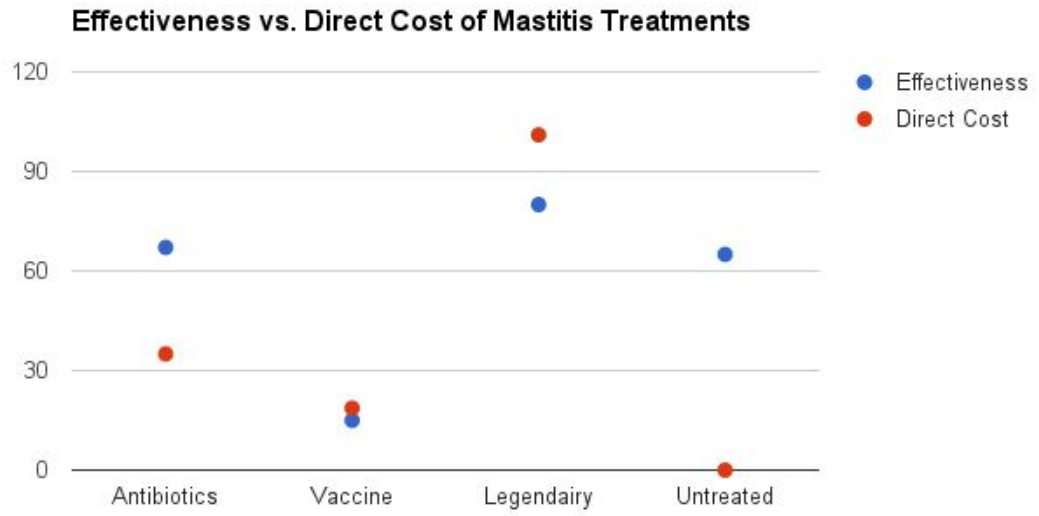
		Lact = 1	Lact > 1	Overall	
		Cost per incident case	Cost per incident case	Cost per incident case	% of total cost
	Diagnostics	$9	$11	$10	2.3
	Therapeutics	$30	$40	$36	8.1
	Non-saleable milk	$18	$30	$25	5.7
Direct costs	Veterinary service	$4	$4	$4	0.9

[6] Rollin, E., Dhuyvetter, K. C., & Overton, M. W. (2015, December). The cost of clinical mastitis in the first 30 days of lactation: An economic modeling tool

	Labor	$19	$22	$21	4.7
	Death loss	$19	$40	$32	7.2
	Direct cost/case	$100	$146	$128	28.9
	Future milk production loss	$149	$111	$125	28.2
	Premature culling loss	$176	$185	$182	40.9
	Future repro. loss	$9	$9	$9	2.0
Indirect costs	Indirect cost per case	$333	$305	$316	71.1
Average cost per case				$444	

a. Results are rounded to the nearest whole US dollar.

Graph 1.[7]



[7] Wilson, D. J., Gonzalez, R. N., Case, K. L., Garrison, L. L., & Groöhn, Y. T. (1999). Comparison of Seven Antibiotic Treatments with No Treatment for Bacteriological Efficacy Against Bovine Mastitis Pathogens. *Journal of Dairy Science, 82*(8), 1664-1670. doi:10.3168/jds.s0022-0302(99)75395-6

Ruegg, P. (2005). Evaluating the Effectiveness of Mastitis Vaccines. *Resources Milk Money*. Retrieved October 19, 2016, from http://milkquality.wisc.edu/wp-content/uploads/2011/09/evaluating-the-effectiveness-of-mastitis-vaccines.pdf

Lysigin | PBS Animal Health. (n.d.). Retrieved October 19, 2016, from http://www.pbsanimalhealth.com/details/Lysigin/20-135553.html

The graph above outlines the effectiveness versus direct cost of the mastitis for different types of treatments. It is important to notice that direct cost does not include cost that profit that is lost due to the sick cow. The indirect costs increases according to the time that cows are sick. Although the cure rates of cows that are untreated and cows that are treated with antibiotics are similar[8], cows that are treated cure faster than the ones that are untreated and as a result, the indirect cost for treated cows is significantly lower than the ones that are untreated. It is also important to note that when antibiotics are used, cows can develop antibiotic resistance and the treatment becomes ineffective. On the hand, cows will not develop resistance to natural proteins so our bacteriocin treatment is more effective.

Barriers to Entry

Ethics

In order to take into consideration the ethics of the project, we must take into consideration the harm that bacteriocins can cause to animals and humans involved in the production and consumption of the dairy industry. Researchers have found bacteriocins to be a lot less harmful than antibiotics in human consumption. There are no known side effects from the consumption of bacteriocins[9]. As for the cows that are being treated with bacteriocins, there has been evidence of irritation of the mammary glands when injected with larger amounts bacteriocins. However, it is important to note that the mammary glands also become irritated by normal injections (7). Due to the irritation of the glands, the milk from these cows that were treated with bacteriocins had clots and flakes. Those symptoms were persisted for 24 hours[10].

Safety for Consumption

Our product would have to undergo guidelines set by the Food and Drugs Administration to be able considered safe for consumption. There will be the need of conducting a study where cows are treated with bacteriocins and the quality of their milk will need to be analyzed. Tests will have to be made to analyze the content of bacteriocins in the milk. The content of nutrients of the will need to be compared to the

[8] Nemec, A. (n.d.). Cow Talk with an Expert: Mastitis Treatments | Dairy Science. Retrieved October 19, 2016, from http://dysci.wisc.edu/2014/08/29/cow-talk-with-an-expert-mastitis-treatments/

[9] Cleveland, J., Montville, T. J., Nes, I. F., & Chikindas, M. L. (2001, December 4). *Bacteriocins: Safe, natural antimicrobials for food preservation*. Retrieved October 19, 2016, from http://www.sciencedirect.com/science/article/pii/S0168160501005608

[10] Wu, J., Hu, S., & Cao, L. (2007). Therapeutic Effect of Nisin Z on Subclinical Mastitis in Lactating Cows . *Antimicrobial Agents and Chemotherapy*, *51*(9), 3131–3135. http://doi.org/10.1128/AAC.00629-07

milk from cows that are not treated with bacteriocins to see if if there are any nutrient difference. It is important to note that there are already several bacteriocins that are present in food that have been approved by the FDA to preserve the food, which means the public has been consuming bacteriocins in their daily lives[11].

Public Doubts about Genetically Modified Organisms

Frequently, the public attach a bad connotation to Genetically Modified Organisms (GMOs), but the public is often poorly educated on the principles and safety protocols for genetic modification. In order to positively market our drug, we need to educate the public about GMOs and start conversations with people about the benefits and the harms of GMOs. Many advances in science have use used GMOs such as insulin production for patients with diabetes. We need to show that our drug's benefits outway the harms it could potentially cause.

Regulation

Food Safety

Bovine mastitis is a health concern when it comes to food safety. When a cow contracts mastitis, its milk contains a higher somatic cell count, and other properties of the milk vary from normal as well. When antibiotic treatments are effectively used to treat mastitis, milk from the ill cow is still not marketable until drug residues have left the cow's system. However there is still a risk of antibiotics getting into the milk. Organic farms do not use antibiotics and therefore must use different methods to treat mastitis, though antibiotics is one of the most standard treatments. Many of the bacteria that cause bovine intramammary infections like mastitis are also the causative agents of human diseases such as *Escherichia coli* and *Staphylococcus aureus*. Most of the time, pasteurization of milk kills the common mastitis-causing bacteria but it usually does not destroy the negative effects of toxins that mastitis pathogens yield. Controlling mastitis, and other diseases like it, is very important to ensuring that dairy products are safe for consumption.

[11] Cleveland, J., Montville, T. J., Nes, I. F., & Chikindas, M. L. (2001, December 4). *Bacteriocins: Safe, natural antimicrobials for food preservation*. Retrieved October 19, 2016, from http://www.sciencedirect.com/science/article/pii/S0168160501005608

Table 3.[12]

Table 1: Comparison of Mastitis Milk with Normal Milk		
Constituent	**Normal Milk**	**Mastitis milk with high SCC**
Fat	3.5	3.2
Lactose	4.9	4.4
Total Protein	3.61	3.56
Total Casein	2.8	2.3
Whey Protein	0.8	1.3 ↑
Serum Protein	0.02	0.07 ↑
Lactoferrin	0.02	0.1 ↑
Immunoglobulin	0.1	0.60 ↑
Sodium	0.057	0.105 ↑
Chloride	0.091	0.147 ↑

Animal Treatment

Since mastitis is a disease that affects the cow's udder, it can be painful to the cow, and severe mastitis is a large problem. Sanitary conditions and milking procedures are important to decrease the risk of intramammary infection. Antibiotics are often used to treat the cow, but organic farms cannot use that method. Mastitis can sometimes get better on its own. When a cow does have mastitis, farmers often use teat dips to maintain the sanitation of the cow's udders, along with intramammary infusions.

Device Regulation

Our device would be an attachment for existing Automatic Milking Installations (AMIs). The FDA has strict regulations on the usage of AMIs that our product would need to adhere to. The shell will not need to go through much regulation because it is not in direct contact with the cow, but is a replacement part for the milking machine.

GMO Regulation

Our product is not a GMO, but a product of GMOs. Considering that our proteins exist in nature and we are just using synthetic biology to produce it in a way that it can actually be used in application, we will not have to through the extensive regulation process for GMO food. We are also using the bacteria in a contained environment and not releasing it. As far as genetic engineering goes, our product is structured as to avoid most

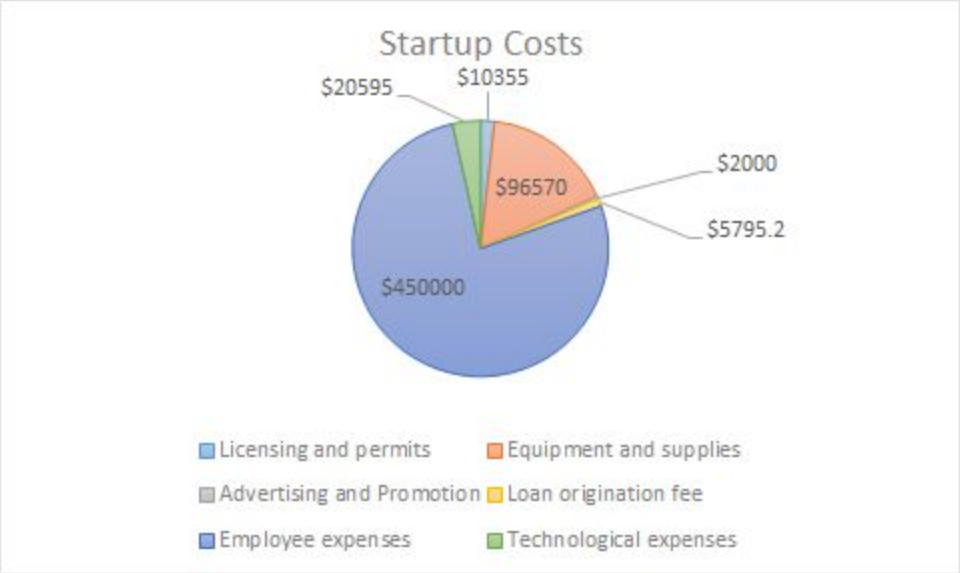
[12] Hamadani, H., Khan, A. A., Banday, M. T., Ashraf, I., Handoo, N., Bashir, A., & Hamadani, A. (2014, February 22). Bovine Mastitis - A Disease for Serious Concern for Dairy Farmers. Retrieved October 19, 2016, from http://en.engormix.com/MA-dairy-cattle/health/articles/bovine-mastitis-disease-serious-t3079/165-p0.htm

regulations. However we do need to go through the approval process for an animal drug. The FDA requires NADA (New Animal Drug Application) approval, which we are planning to apply for.

Economy of the Business

Start-up Costs

We estimate startup costs to be a minimum of $585,315 for the first year, with equipment and computers (in technological expenses) incurring a one-time fixed cost and the majority of other portions being annual costs:



Costs breakdown:

	Object	Cost ($)
License and permit fees	**FDA approval**	**7035**
	Patent	**1240**
	Drug license	**2080**
	Total	**10,355**
Equipment and supplies (machinery)	**Sieve**	**1100**
	Grinding and stirring	**7470**
	Sterilizing	**60,000**

	Mixing	**20,000**
	Granulator	**2000**
	Filling and sealing	**6000**
	Total	**96,570**
Advertising and Promotion	**Online**	**1500**
	Physical (paper, poster)	**500**
	Total	**2000**
Loan fees	**Origination fee**	**5795.2**
	Total	**5795.2**
Employee Expenses	**# Employees**	**15**
	Salary	**30,000**
	Total (first year)	**450,000**
Technological Expenses	**Website**	**0**
	Software - Office package	**4600**
	Software - Geneious	**995**
	Computers	**15000**
	Total	**20595**
	Startup costs total	**585315.2**

Revenue Drivers

Legendairy is centered on three main revenue drivers: Udder Defense (mastitis treatment peptide), The Milky Way Customizable Shell (mastitis prevention milking shell), CowScope (mastitis detection mobile app). Our bacteriocin injection and our customized shell will be the primary revenue streams. The bacteriocin injection will have to be replenished by dairy farmers as more cases of mastitis appear on their farm. The

milking shell will need to be replaced if damaged or wore down. Finally, our third revenue source is our mobile app including the additional microscope add on. If the app and microscope are installed at every dairy farm in the US, this product will bring a fair amount of revenue.

Marketing Plan

Marketing Strategy

Our products specially target small and medium scale dairy farmers. We found that larger farms have more established and rigid systems, making them less open to adopting new technologies. However, after scaling up our technologies it may be appealing to larger farms. We found that many farmers like to build their own gear and customize their process to their liking. With the modular design of our milking machine device and the wide selection of bacteriocin treatments, we are accommodating to this desire. While marketing it will be very important to emphasize the customizability and the control that the farmers will have.

We have a unique selling proposition in that we could be the only non-antibiotic effective treatment for bovine mastitis on the market. This is significant because antibiotics are not favorable for multiple reasons. Due to the heavy use of traditional antibiotic mastitis treatments in dairy farms, the pathogens are gain resistance. Antibiotic resistance is a growing problem that is making mastitis a more significant and difficult issue. Also, despite heavy precautions, antibiotics still end up in milk sold to consumers. This is a public health issue and many people have allergies to these antibiotics. When marketing our product we must emphasize the decrease in the use of antibiotics. Dairy customers themselves may prefer to buy milk from farms that use bacteriocins opposed to antibiotics. In short bacteriocins are a much safer and more natural alternative to antibiotics and should be marketed as such.

Product Distribution

We will be selling 13 different bacteriocin gels, each with a different purpose. The farmers will also be able to mix these treatments case by case. The milking shell will be sold with the basic shell that will attach to the milking machine. The four additional modules (UV light, automated teat dipping, cold shock, temperature sensor) will be purchased separately to increase the functionality in preventing mastitis. The mobile application will be available for free but we will be selling the companion microscope device.

Sales Process & Tactics

We will be selling our products directly to small and medium scale farms. We will be working heavily with our customers to provide a customized solution for each farm.

Design and Development Plan

Development Status

Legendairy is in the process of becoming a legal company. We are working toward getting a patent on our products and on making them mass marketable for our target consumers. When the company has officially started, Cornell University and the members of the Cornell iGEM project team will own it.

Intellectual Property

We are currently planning the process of obtaining patenting rights through Cornell University's Center for Technology Licensing. We hope to patent our milking shell designs. We are also developing formulas for the bacteriocin gels involving mixtures of our proteins. These will be optimized and be confidential intellectual property.

Company Structure

The following list demonstrates the company structure Legendairy will assume upon foundation:

- Board of Directors (including CEO, COO, CTO)
    - Finance
        - Manages taxes, capital and costs
    - Human Resources
        - Responsible for recruitment and payroll
    - Research and Development
        - Biology Division
            - Accountable for drug development and clinical trials
        - Engineering Division
            - Perform product optimization and trials
    - Manufacturing
        - Pharmaceutical Division

        - Large scale drug production
    - Prevention Division
        - Large scale production of mastitis prevention product manufacture
    - Detection and Monitoring Division
        - Large scale production of detection and monitoring systems
    - Packaging Division
        - Large scale production of product packaging
- Information Technology
    - Includes modeling, software development, mobile app development, website maintenance
- Marketing
    - Identify new markets, advertise products, community outreach, public relations)

Company Development Schedule

October 2016	iGEM competition
November 2016	Development of preventative mastitis-inducing pathogens bacteriocins into gel
	Finalize product design
	Extensive laboratory testing
December 2016	Apply for patents
	Apply for copyrights
	Finalize app launch into Apple Store
January 2017	Legally establish Legendairy

	Begin clinical trial application process